POMERANTZ LLP
Jennifer Pafiti (SBN 282790)
1100 Glendon Avenue, 15th Floor
Los Angeles, California 90024
Telephone: (310) 405-7190
jpafiti@pomlaw.com

Attorney for Plaintiff

[Additional Counsel on Signature Page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

KAREN MITCHAM, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

TALIS BIOMEDICAL CORPORATION, BRIAN COE, J. ROGER MOODY, JR., FELIX BAKER, RAYMOND CHEONG, MELISSA GILLIAM, RUSTEM F. ISMAGILOV, KIMBERLY J. POPOVITS, MATTHEW L. POSARD, and RANDAL SCOTT,

Defendants.

Case No.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiff Karen Mitcham ("Plaintiff"), individually and on behalf of all others similarly situated, by and through Plaintiff's attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, the investigation conducted by Plaintiff's counsel, which includes without limitation: (a) review and analysis of regulatory filings made by Talis Biomedical Corporation ("Talis" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Talis; and (c) review of other publicly available information concerning Talis.

NATURE OF THE ACTION

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Talis common stock pursuant and/or traceable to the registration statement and prospectus (collectively, the "Registration Statement") issued in connection with the Company's February 2021 initial public offering ("IPO" or the "Offering"). Plaintiff pursues claims against Defendants under the Securities Act of 1933 (the "Securities Act").

2. Talis purportedly develops diagnostic tests to enable accurate, reliable, low cost, and rapid molecular testing for infectious diseases and other conditions at the point-of-care. The Talis One tests are being developed for respiratory infections, infections related to women's health, and sexually transmitted infections.

3. On February 12, 2021, the Company filed its prospectus on Form 424B4 with the SEC, which forms part of the Registration Statement. In the IPO, the Company sold 15,870,000 shares of common stock at a price of $16.00 per share. The Company received net proceeds of approximately $232.6 million from the Offering. The proceeds from the IPO were purportedly to be used for commercial

activities (including the hiring and training of sales and marketing personnel), research and development, and working capital and other general corporate purposes.

4. On March 8, 2021, Talis announced that it had withdrawn its Emergency Use Authorization ("EUA") application for the Talis One COVID-19 test. In a press release, the Company revealed that "[i]n late February, the FDA informed the company that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support Talis's EUA application." As a result, Talis "intends to initiate its previously planned clinical validation study in a point-of-care environment" to submit its EUA application "early in the second quarter of 2021." This study "was designed with a different comparator study, which Talis believes will address the FDA's concerns."

5. On this news, the Company's stock price fell $1.80, or 12%, to close at $12.85 per share on March 8, 2021.

6. Then, on August 10, 2021, Talis revealed that its "development timelines have been extended by delays in the launching of [Talis's] COVID-19 test and manufacturing scale." As a result, Talis "expect[s] to see [its] first meaningful revenue ramp in 2022."

7. On this news, the Company's stock price fell $0.58, or 6%, to close at $8.39 per share on August 11, 2021, on unusually heavy trading volume.

8. On August 30, 2021, after the market closed, Talis announced that its Chief Executive Officer ("CEO"), Brian Coe ("Coe"), had "stepped down" as President, CEO, and Director.

9. On this news, the Company's stock price fell $1.00, or 11%, to close at $8.06 per share on August 31, 2021, on unusually heavy trading volume.

10. On November 15, 2021, Talis announced that Brian Blaser ("Blaser") was appointed as President, CEO, and Director of Talis effective December 1, 2021. However, a week after his appointment, on December 8, 2021, Talis announced that Blaser had stepped down from his positions.

11. On this news, the Company's stock price fell $0.55, or more than 11%, to close at $4.28 per share on December 8, 2021.

12. By the commencement of this action, Talis stock has traded as low as $3.81 per share, a more than 76% decline from the $16.00 per share IPO price.

13. The Registration Statement was false and misleading and omitted to state material adverse facts. Specifically, Defendants failed to disclose to investors: (1) that the comparator assay in the primary study lacked sufficient sensitivity to support Talis's EUA application for the Talis One COVID-19 test; (2) that, as a result, Talis was reasonably likely to experience delays in obtaining regulatory approval for the Talis One COVID-19 test; (3) that, as a result, the Company's commercialization timeline would be significantly delayed; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis.

14. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

15. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77k and 77o).

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 22 of the Securities Act (15 U.S.C. § 77v).

17. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b). Talis is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

18. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

19. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased or otherwise acquired Talis common stock pursuant and/or traceable to the Registration Statement issued in connection with the Company's IPO, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

20. Defendant Talis is incorporated under the laws of Delaware with its principal executive offices located in Menlo Park, California. Talis's common stock trades on the NASDAQ under the symbol "TLIS."

21. Defendant Coe was, at all relevant times, the CEO and a director of the Company, and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

22. Defendant J. Roger Moody, Jr. ("Moody") was, at all relevant times, the Chief Financial Officer of the Company, and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

23. Defendant Felix Baker ("Baker") was a director of the Company and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

24. Defendant Raymond Cheong ("Cheong") was a director of the Company and signed or authorized the signing of the Company's Registration Statement filed with the SEC

25. Defendant Melissa Gilliam ("Gilliam") was a director of the Company and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

26. Defendant Rustem F. Ismagilov ("Ismagilov") was a director of the Company and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

27. Defendant Kimberly J. Popovits ("Popovits") was a director of the Company and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

28. Defendant Matthew L. Posard ("Posard") was a director of the Company and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

29. Defendant Randal Scott ("Scott") was a director of the Company and signed or authorized the signing of the Company's Registration Statement filed with the SEC.

30. Defendants Coe, Moody, Baker, Cheong, Gilliam, Ismagilov, Popovits, Posard, and Scott are collectively referred to hereinafter as the "Individual Defendants."

31. Talis and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

32. Talis purportedly develops diagnostic tests to enable accurate, reliable, low cost, and rapid molecular testing for infectious diseases and other conditions at the point-of-care. The Talis One tests are being developed for respiratory infections, infections related to women's health, and sexually transmitted infections.

Materially False and Misleading Statements Issued in the Registration Statement

33. On February 11, 2021, the Company filed its final amendment to the Registration Statement with the SEC on Form S-1/A, which forms part of the Registration Statement. The Registration Statement was declared effective the same day.

34. On February 12, 2021, the Company filed its prospectus on Form 424B4 with the SEC, which forms part of the Registration Statement. In the IPO, the Company sold 15,870,000 shares of common stock at a price of $16.00 per share. The Company received net proceeds of approximately

$232.6 million from the Offering. The proceeds from the IPO were purportedly to be used for commercial activities (including the hiring and training of sales and marketing personnel), research and development, and working capital and other general corporate purposes.

35. The Registration Statement was negligently prepared and, as a result, contained untrue statements of material facts or omitted to state other facts necessary to make the statements made not misleading, and was not prepared in accordance with the rules and regulations governing its preparation.

36. Under applicable SEC rules and regulations, the Registration Statement was required to disclose known trends, events or uncertainties that were having, and were reasonably likely to have, an impact on the Company's continuing operations.

37. The Registration Statement disclosed the following about Talis's regulatory strategy for the Talis One test to diagnose COVID-19 and its production timeline, stating that the Company had submitted its EUA application to the U.S. Food and Drug Administration ("FDA") in January 2021[1]:

> We are developing Talis One tests for respiratory infections, infections related to women's health and sexually transmitted infections. ***In January 2021, we submitted a request for an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for our Talis One platform with COVID-19 molecular diagnostic assay for the automated detection of nucleic acid from the SARS-CoV-2 virus in nasal swab samples from individuals suspected of COVID-19 by their healthcare provider***. Our regulatory strategy is to initially submit for the equivalent of a CLIA-moderate authorization to be followed shortly thereafter with a subsequent filing for the equivalent of a CLIA-waived authorization for use in non-laboratory settings. We are also developing influenza A and influenza B tests to be included as part of a respiratory panel with our COVID-19 test (COVID-Flu Panel). In addition, we plan to initiate a clinical trial to support clearance of a pre-market notification under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) of our Talis One instrument with a test for chlamydia and gonorrhea in the second half of 2021 and submit a 510(k) pre-market notification in the first half of 2022. To support our anticipated commercial launch of our COVID-19 test, we have invested in automated cartridge manufacturing lines capable of producing one million cartridges per month, which are scheduled to begin to come on-line in the first quarter of 2021 and we expect will scale to full capacity through 2021. We estimate that the potential annualized market opportunity for COVID-19 point-of-care diagnostic tests in the United States exceeds $7.0 billion.

[1] Unless otherwise stated, all emphases in bold and italics hereinafter is added.

38. Regarding the data used to assess the performance of the Talis One platform, the Registration Statement stated:

> *Performance of the Talis One COVID-19 test*
>
> As part of our development of our COVID-19 test we assessed the performance of the Talis One platform using anterior or mid-turbinate nasal specimens to tests conducted in a centralized laboratory using the Centers for Disease Control and Prevention (CDC) quantitative polymerase chain reaction assay. In a preclinical assessment comparing the Talis One platform to a reference lab test on 60 matched anterior or mid-turbinate nasal specimens, the Talis One test results exactly matched the central lab results with 100% positive percentage agreement (PPA) and 100% negative percentage agreement (NPA) for detection of SARS-CoV-2, the virus that causes COVID-19. ***The high PPA and NPA is suggestive of clinical sensitivity and specificity in the broader clinical population*** and is driven by the very low limits of detection possible on the Talis One platform, e.g. 500 viral particles per milliliter.

39. The Registration Statement purported to warn of certain risks impacting Talis's EUA application for the Talis One for COVID-19, stating, in relevant part:

> ***There can be no assurance that the COVID-19 test we are developing for the detection of the SARS-CoV-2 virus will be granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). If no EUA is granted or, once granted, it is revoked or the emergency declaration is terminated, we will be unable to sell this product in the near future and will be required to pursue 510(k) clearance or other marketing authorization, which would likely be a lengthy and expensive process.***
>
> We submitted a request for an EUA to the FDA in January 2021 for our Talis One platform with COVID-19 molecular diagnostic assay for the automated detection of nucleic acid from the SARS-CoV-2 virus in nasal swab samples from individuals suspected of COVID-19 by their healthcare provider. Our regulatory strategy is to initially submit for the equivalent of a CLIA-moderate authorization to be followed shortly thereafter with a subsequent filing for the equivalent of a CLIA-waived authorization for use in non-laboratory settings. ***During its preliminary review of our EUA submission, the FDA requested that we provide it with additional information on our test prior to initiating its substantive review of the submission, which we expect to promptly provide. There can be no assurances that the FDA will authorize either of these requests and if we do not receive both authorizations, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.***
>
> An EUA would allow us to market and sell our platform with this assay without the need to pursue the lengthy and expensive 510(k) clearance process or any other marketing authorization process. The FDA may issue an EUA during a public health emergency if it determines that, based on the totality of the scientific evidence, that it is reasonable to

> believe that the product may be effective, that the known and potential benefits of a product outweigh the known and potential risks, that there is no adequate, approved and available alternative and if certain additional regulatory criteria are met. These standards for marketing authorization are lower than if the FDA were to review our test under its traditional marketing authorization pathways, and we cannot assure you that our COVID-19 test would be cleared or approved under those more onerous clearance and approval standards. ***As a result, if we do not receive an EUA for our Talis One platform with COVID-19 test, the commercial launch of such products could be significantly delayed, which would adversely impact our business, financial condition and results of operations.*** The effects of any such delay would also be exacerbated if the demand for COVID-19 tests declines prior to our receipt of any marketing authorization.

(First emphasis in original.)

40. The Registration Statement was materially false and misleading and omitted to state: (1) that the comparator assay in the primary study lacked sufficient sensitivity to support Talis's EUA application for the Talis One COVID-19 test; (2) that, as a result, Talis was reasonably likely to experience delays in obtaining regulatory approval for the Talis One COVID-19 test; (3) that, as a result, the Company's commercialization timeline would be significantly delayed; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis.

The Truth Emerges

41. On March 8, 2021, Talis announced that it had withdrawn its EUA application for the Talis One COVID-19 test. In a press release, the Company revealed that "[i]n late February, the FDA informed the company that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support Talis's EUA application." As a result, Talis "intends to initiate its previously planned clinical validation study in a point-of-care environment" to submit its EUA application "early in the second quarter of 2021." This study "was designed with a different comparator study, which Talis believes will address the FDA's concerns."

42. On this news, the Company's stock price fell $1.80, or 12%, to close at $12.85 per share on March 8, 2021.

43. Then, on August 10, 2021, Talis reported its second quarter 2021 financial results in a press release, which stated that the Company had "[c]ompleted a clinical validation study for Talis One COVID-19 assay in a point-of-care environment to support an Emergency Use Authorization (EUA) application submission to the FDA" and that it had "[s]ubmitted an EUA application for Talis One System and Talis One COVID-19 Assay to the FDA on July 23, 2021." However, during the related conference call, Defendant Coe revealed that its "development timelines have been extended by delays in the launching of [Talis's] COVID-19 test and manufacturing scale." Defendant Moody stated that "[i]t's difficult to predict how much product revenue we will recognize this year, given the uncertainty around the timing of the EUA, our controlled launch, manufacturing scale-up and the variability of COVID testing market." He went on to state that Talis "expect[s] to see [its] first meaningful revenue ramp in 2022."

44. On this news, the Company's stock price fell $0.58, or 6%, to close at $8.39 per share on August 11, 2021, on unusually heavy trading volume.

45. On August 30, 2021, after the market closed, Talis announced that Defendant Coe had "stepped down" as President, CEO, and Director.

46. On this news, the Company's stock price fell $1.00, or 11%, to close at $8.06 per share on August 31, 2021, on unusually heavy trading volume.

47. On November 15, 2021, Talis announced that Blaser was appointed as President, CEO, and Director of Talis effective December 1, 2021. However, a week after his appointment, on December 8, 2021, Talis announced that Blaser had stepped down from his positions.

48. On this news, the Company's stock price fell $0.55, or more than 11%, to close at $4.28 per share on December 8, 2021.

49. By the commencement of this action, Talis stock has traded as low as $3.81 per share, a more than 76% decline from the $16.00 per share IPO price.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

50. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Talis common stock pursuant and/or traceable to the Company's false and/or misleading Registration Statement issued in connection with the Company's IPO, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

51. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. The Company sold 15,870,000 shares of common stock in the IPO. Moreover, record owners and other members of the Class may be identified from records maintained by Talis or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

52. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

53. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

54. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the Securities Act was violated by Defendants' acts as alleged herein;

(b) whether the Registration Statement and statements made by Defendants to the investing public in connection with the Company's IPO omitted and/or misrepresented material facts about the business, operations, and prospects of Talis; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

55. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

(Violations of Section 11 of the Securities Act Against All Defendants)

56. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

57. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of the Class, against the Defendants.

58. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

59. Talis is the registrant for the IPO. The Defendants named herein were responsible for the contents and dissemination of the Registration Statement.

60. As issuer of the shares, Talis is strictly liable to Plaintiff and the Class for the misstatements and omissions.

61. None of the Defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement was true and without omissions of any material facts and were not misleading.

62. By reasons of the conduct herein alleged, each Defendant violated, and/or controlled a person who violated, Section 11 of the Securities Act.

63. Plaintiff acquired Talis shares pursuant and/or traceable to the Registration Statement for the IPO.

64. Plaintiff and the Class have sustained damages. The value of Talis common stock has declined substantially subsequent to and because of the Defendants' violations.

COUNT II

(Violations of Section 15 of the Securities Act Against the Individual Defendants)

65. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

66. This Count is asserted against the Individual Defendants and is based upon Section 15 of the Securities Act.

67. The Individual Defendants, by virtue of their offices, directorship, and specific acts were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Talis within the

meaning of Section 15 of the Securities Act. The Individual Defendants had the power and influence and exercised the same to cause Talis to engage in the acts described herein.

68. The Individual Defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Plaintiff and the Class.

69. By virtue of the conduct alleged herein, the Individual Defendants are liable for the aforesaid wrongful conduct and are liable to Plaintiff and the Class for damages suffered.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: February 18, 2022

Respectfully submitted,

POMERANTZ LLP

/s/ Jennifer Pafiti

Jennifer Pafiti (SBN 282790)
1100 Glendon Avenue, 15th Floor
Los Angeles, California 90024
Telephone: (310) 405-7190
jpafiti@pomlaw.com

POMERANTZ LLP
Jeremy A. Lieberman
(*pro hac vice* application forthcoming)
J. Alexander Hood II
(*pro hac vice* application forthcoming)
600 Third Avenue, 20th Floor
New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
jalieberman@pomlaw.com
ahood@pomlaw.com

Attorneys for Plaintiff